

## **REMARKS**

### **I. Preliminary Remarks**

Claims 20-23, 25, and 28-31 are under consideration and are rejected. After entry of this paper, Claims 12-19, and 32-75 are withdrawn with traverse and without prejudice as being drawn to non-elected invention. Claims 1-11, 21, 24, 26-27, and 76-83 are canceled. Claims 20, 22-23, 25, and 28-31 remain under consideration. In this response, Applicant addresses each of the rejections raised by the Examiner. Support for the amendments to the claims is found throughout the specification. The amendments do not include new matter. Reconsideration and withdrawal of the rejections are solicited for the reasons set out below. Applicant respectfully submits that the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

This Response is filed with a petition for a three-month extension of time. The USPTO is given authorization to charge any fees necessary with this submission, and to credit any over payment of fees, to Applicants' Deposit Account No. 16-1445.

### **II. Patentability Arguments**

#### **A. The Obviousness Rejection of Claims 20-23, 25, and 28-31 under 35 U.S.C. §103(a) May Be Properly Withdrawn.**

As stated in the MPEP (§2141), to support an obviousness rejection, four basic criteria must be met. These are (A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined. Clearly for prior art to render an invention obvious, it must render obvious the whole invention and not merely some part of the invention (*In re Antonie* 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1997)). The prior art must also be considered as a whole including parts that teach away from Applicant's invention. Applicant respectfully submits that these criteria are not met in the Examiner's rejections.

The Examiner has maintained the rejection of claims 20-23, 25, and 28-31 under 35 U.S.C. 103(a) as being unpatentable over Bowland, et al., (Canadian Veterinary Journal, Jan

2000, Vol. 41, No. 1, pages 33-48) and Fulton, et al., (Vaccine, 15 September 2000, Vol. 19, No. 2-3, pages 264-274) in view of Brake, et al., (US Patent No. 6,787,146, Sept 2004; publication US2002/0058046, 16 May 2002). Applicants respectfully traverse this rejection.

Applicants have amended claim 20 to recite, in part, "A microfluidized vaccine composition comprising: ..." Support for this amendment is found in Example 6 of the specification and in the section entitled "Inactivated (Partial or Whole Cell) and Modified Live Vaccines."

As stated by the Examiner, "Bowland et al. do not teach a vaccine composition comprising BVDV types 1 and 2. Bowland et al. do not teach a vaccine composition with an adjuvant comprising Quil A, Amphigen (lecithin and oil blend) and cholesterol." In addition, Bowland do not teach microfluidized compositions. Thus, Bowland do not teach or suggest Applicants' invention.

Fulton describe vaccines comprising BVDV types 1 and 2 but makes no mention of an adjuvant or of microfluidized compositions. Thus, Fulton do not teach or suggest Applicants' invention.

Brake describe a parasite vaccine while Applicant's invention comprises viral and bacterial vaccines. Brake describe a homogenate vaccine while Applicant's invention comprises whole virus or whole bacteria vaccines. Thus, while Brake demonstrate that the adjuvant works for a homogenate parasite vaccine, they do not demonstrate that the adjuvant works in a whole cell viral vaccine. Brake also do not mention microfluidized compositions. Thus, Brake do not teach or suggest Applicants' invention.

The Applicants respectfully submit that none of the references cited by the Examiner render Applicants' invention obvious. Bowland does not teach or suggest Applicants' invention. Combining the secondary references of Fulton and Brake with Bowland does not make up for the deficiencies in Bowland. Even when combined the references do not yield Applicants' invention. That is, the combination of the references does not yield a microfluidized vaccine composition comprising a modified live Bovine Herpes Virus (BHV-1); a modified live parainfluenza virus Type 3 (PI3); a modified live Bovine Respiratory Syncytial Virus (BRSV); a Bovine Viral Diarrhea Virus Type-1 (BVDV-1); a Bovine Viral

Diarrhea Virus Type-2 (BVDV-2); at least one antigen selected from the group consisting of *Leptospira canicola*, *Leptospira grippityphosa*, *Leptospira borgpetersenii hardjo-prajitno*, *Leptospira icterohaemorrhagiae*, *Leptospira interrogans pomona*, *Leptospira borgpetersenii hardjo-bovis* and *Campylobacter fetus*; an adjuvant; and a veterinary-acceptable carrier.

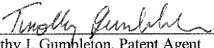
Claim 21 has been canceled, rendering this rejection moot as to this claim.

Accordingly, it is respectfully submitted that the vaccine compositions, as presently claimed, are not rendered obvious by Bowland, et al., and Fulton et al. in view of Brake et al. Thus, based on the remarks presented herein, when combined with the arguments provided in the responses to the prior office actions in this application, the rejection of claims 20-23, 25, 28-31 under 35 U.S.C. 103(a) is overcome. Withdrawal of the rejection is respectfully requested.

### III. Conclusion.

In view of the remarks made herein, Applicants respectfully submit that Claims 20, 22-23, 25, and 28-31 are in condition for allowance and request notification of same.

Respectfully submitted,

  
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